**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

POLYZEN, INC.
1041 Classic Road
Apex, North Carolina 27539
Plaintiff
v.

DIELECTRICS, INC.
300 Burnett Road
Chicopee, Massachusetts 01020
Defendant

Civil Action No. ___________

## COMPLAINT FOR PATENT INFRINGEMENT

This is an action by Polyzen, Inc. for patent infringement claims under 35 U.S.C. §§ 271, 281, 283, 284 and/or 285, for infringement of United States Patent No. 9,737,694 by Defendant Dielectrics, Inc.

## JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over Polyzen's claims, pursuant to patent infringement under 28 USC 1331 and 1338.

2. Defendant Dielectrics is engaged in manufacturing medical devices, including prostate immobilization balloons at issue in this case, which are sold throughout the United States. Jurisdiction and Venue are proper in this District because Defendant is located in this District. This Court has personal jurisdiction over Defendant.

3. Venue is proper in this judicial district pursuant to 28 U.S.C. 1391 and 1400(b).

## PARTIES

4. Polyzen is a company organized under the laws of North Carolina, with a place of business at 1041 Classic Road, Apex, North Carolina 27539. Polyzen is in the business of developing and manufacturing medical products and devices, including medical balloons, for medical industry original equipment manufacturers. Polyzen invested significant resources in the development of a unique and proprietary method for the manufacture of prostrate immobilization balloons. Polyzen patented the method of manufacture of prostate immobilization balloon devices at issue in this case.

5. Defendant Dielectrics is a corporation organized and existing under the laws of the State of Massachusetts, with a principal place of business located at 300 Burnett Road, Chicopee, Massachusetts 01020. Defendant Dielectrics manufactures, sells, and offers for sale various medical devices in the United States, including the prostate immobilization balloon devices at issue in this case.

## GENERAL ALLEGATIONS

6. Polyzen developed a unique and valuable method for the manufacture of a various medical balloon devices. Polyzen used this method to make a variety of medical balloons, including the manufacture of a hundred thousands prostate immobilization balloons sold to RadiaDyne, Inc. in 2007 through 2009.

7. On September 25, 2007, Polyzen filed a provisional patent application on its method of manufacture. On September 25, 2008, Polyzen filed a non-provisional application which published as 2015/0,182,229 on July 2, 2015 and as 2015/0,190,142 on July 9, 2015 and as 2013/0,085,324 on April 4, 2013 and as 2011/0,295,202 on December 1, 2011 and as

2010/0,137,797 on June 3, 2010 and as 2009/0,082,724 on March 26, 2009.

8. On August 22, 2017, U.S. Patent 9,737,694 titled Multi-Layer Film Welded Articulated Balloon, issued to Polyzen.

7. In 2008, Defendant Dielectrics began using Polyzen's patented method to manufacture prostate immobilization balloons for RadiaDyne. The method used by Dielectrics to manufacture prostate immobilization balloons for RadiaDyne infringes numerous claims of the '694 patent.

8. At least as early as March 27, 2013, Dielectrics has had notice of the earlier of the above publications.

**COUNT I**
**PATENT INFRINGEMENT OF US PATENT NO. 9,737,694**

9. On August 22, 2017, the United States Patent and Trademark Office ("USPTO") duly and properly issued United States Patent No. 9,737,694, entitled Multi-Layer Film Welded Articulated Balloon.

10. Polyzen is the sole assignee of the '694 patent pursuant to assignment.

11. The '694 patent grants protection to Polyzen's claimed Multi-Layer Film Welded Articulated Balloon and includes independent claim 1, which describes the protected invention:

> Claim 1. A method for the fabrication of an articulable medical balloon device configured for use in an in vivo medical procedure, said method comprising the steps of
> (a) providing at least two elongate film layers having opposed peripheral edges;
> (b) sealing said opposed peripheral edges to form an elongate compartment adapted to receive fluid to expand said film layers relative to each other, said elongate compartment having a closed distal end and a proximal neck portion;
> (c) providing an opening at said proximal neck portion of said elongate fluid compartment that is adapted to receive a lumen so that the lumen is aligned with an elongate direction of the elongate compartment; and
> (d) sealing at least one of said layers to a third layer, intermediate said opposed peripheral edges, to form a subcompartment in fluid communication with said

compartment that is configured to enable the device to articulate to a predetermined shape and dimension for said in vivo medical procedure, said predetermined shape comprising an upwardly bulging distal portion of the elongate compartment, wherein said two elongate film layers are sealed to one another at peripheral edges thereof.

12. Defendant manufactures, uses, offers for sale and sells a multi-layer film welded medical balloon, identified as an Immobilizer Treatment Device rectal balloon and/or Immobilizer and/or ImmobiLoc, and/or IPSI and/or Alatus Balloon as well as other like products ("Dielectrics Products") such activities of Dielectrics constitute infringement of the '694 patent under 35 U.S.C. §§ 271, 281, 283, 284 and/or 285.

13. The Dielectric Products are manufactured in a manner which infringes the claims of the '694 patent under 35 U.S.C. §§ 271, 281, 283, 284 and/or 285. The ImmobiLoc and IPSI infirnge claims 1-10 and 12-30. The Alatus infringes claims 1-7, 9, 10 and 12-18. The nature of the infringement is detailed in the attached claim charts.

14. The Dielectrics Products are articulable medical balloon devices configured for use in an in vivo medical procedure, manufactured by:

(a) providing at least two elongate film layers having opposed peripheral edges;
(b) sealing said opposed peripheral edges to form an elongate compartment adapted to receive fluid to expand said film layers relative to each other, said elongate compartment having a closed distal end and a proximal neck portion;
(c) providing an opening at said proximal neck portion of said elongate fluid compartment that is adapted to receive a lumen so that the lumen is aligned with an elongate direction of the elongate compartment; and
(d) sealing at least one of said layers to a third layer, intermediate said opposed peripheral edges, to form a subcompartment in fluid communication with said compartment that is configured to enable the device to articulate to a predetermined shape and dimension for said in vivo medical procedure, said predetermined shape comprising an upwardly bulging distal portion of the elongate compartment, wherein said two elongate film layers are sealed to one another at peripheral edges thereof.

15. Upon information and belief, Defendant has infringed and continues to infringe claims 1 through 30 of the '694 patent, as illustrated in the attached claim charts.

16. Upon information and belief, Defendant has infringed and continues to infringe

the claims of the ‘694 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, the Dielectrics Products within the United States.

17. The Dielectrics Products are fabricated as taught and claimed in the ‘694 patent in suit and include all of the elements recited in Claims 1 through 30 of the ‘694 patent.

18. Defendant’s infringement is a literal infringement and/or infringement under the doctrine of equivalents, and is direct and indirect.

19. Polyzen is entitled to recover from the Defendant the damages sustained, including a reasonable royalty and/or lost profits of Polyzen and/or profits of Defendant as a result of Defendant’s infringing acts.

20. Defendant has had knowledge of Polyzen’s rights in the ‘694 patent and has continued infringement with full knowledge of and in disregard for those rights, wherein such actions constitute willful infringement.

21. Defendant will continue to infringe the claims of Polyzen’s ‘694 patent unless enjoined by this Court.

22. Defendant’s infringement of the ‘694 patent has damaged Polyzen and will continue to cause Polyzen substantial irreparable harm unless enjoined by this Court.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff Polyzen prays that this Court enter judgment that:

23. The asserted claims of the '694 patent are infringed by Defendant;

24. Defendant's infringement of the '694 patent has been willful;

25. Defendant, and its customers, licensees, directors, officers, agents, servants, employees and all other persons in active concert or privity or in participation with it, be preliminarily and permanently enjoined from manufacturing, using, selling, offering to sell, and importing the Accused Product, and any other infringing products, in and into the United States, directly or indirectly, prior to expiration of the '694 patent;

26. Defendant be enjoined to deliver upon oath, to be impounded during the pendency of this action, and delivered to Polyzen pursuant to judgment herein, all originals, copies, facsimiles, or duplicates of any device shown to infringe Polyzen's '694 patent;

27. Judgment be awarded to Polyzen under 35 U.S.C. §§ 271, 281, 283, 284 and/or 285;

28. Judgment be entered for Polyzen against Defendant, for Polyzen's actual damages, for reasonable royalties or for any profits attributable to infringements of Polyzen's '694 patent.

29. Defendant be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law;

30. Polyzen be awarded damages adequate to compensate for Defendant's infringement of the '694 patent, and that such damages be trebled pursuant to 35 U.S.C. § 284;

31. This case is exceptional within the meaning of 35 U.S.C. § 285, and all costs and

expenses of this action, including reasonable attorneys' fees, be awarded to Polyzen; and

32. Polyzen be awarded such further relief as this Court deems necessary, just and/or proper.

**DEMAND FOR JURY TRIAL**

Plaintiff Polyzen demands a trial by jury of all issues so triable.

Respectfully submitted, this 19th day of September 2017.

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